New as of: 08.2015

sirona
The Dental Company

HELIODENT PLUS

Operating Instructions

English

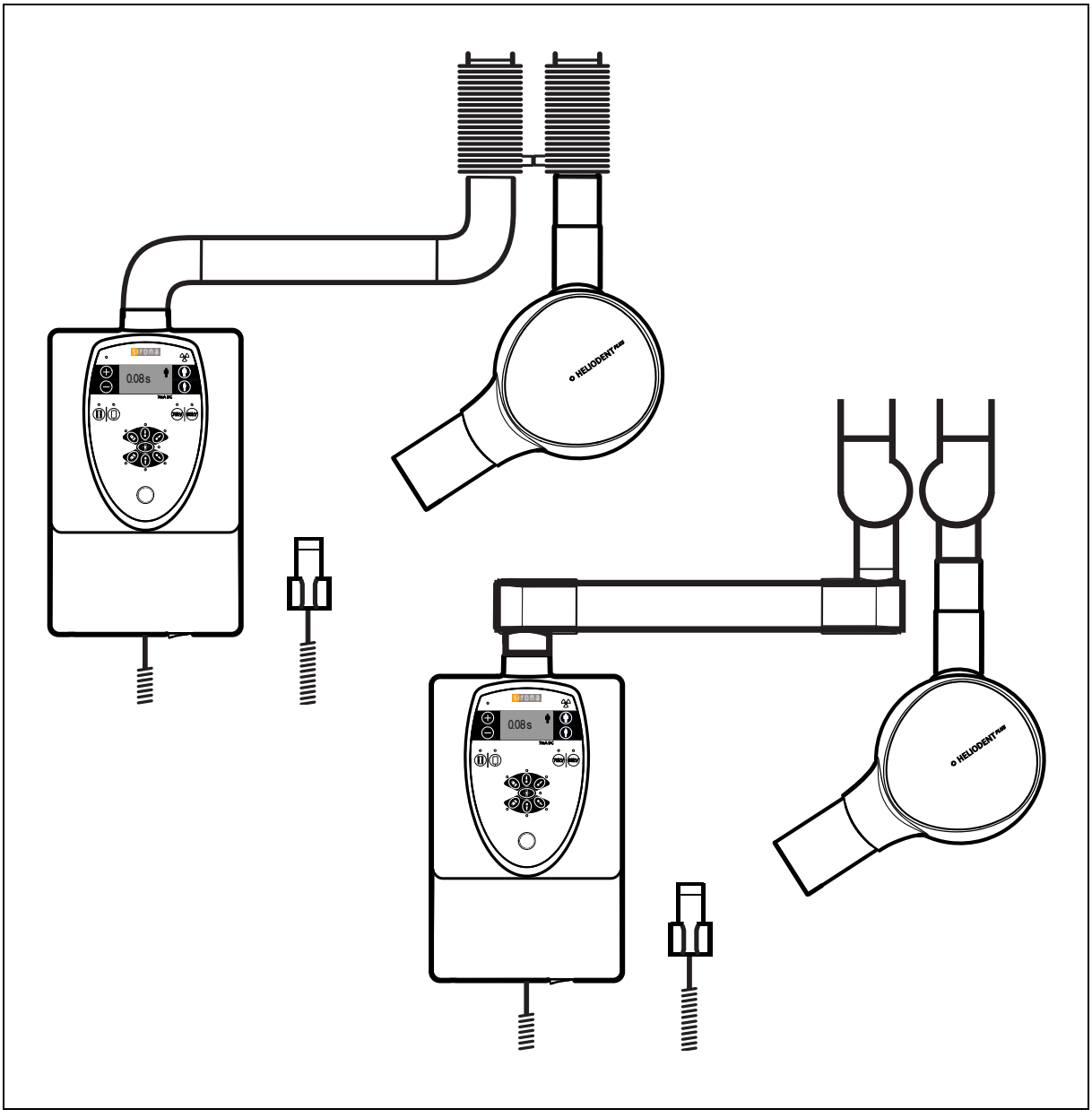

Table of contents

1 General data

1.1 Preface

Dear Customer,

Thank you for purchasing the HELIODENT^{PLUS} X-ray system.

This system can be used to take intraoral X-rays.

Please familiarize yourself with the unit by reading through these **Operating Instructions** before taking any X-rays of patients.
Please comply with the applicable **radiation protection regulations** and **warnings** at all times.

SIRONA requires regular constancy tests to ensure image quality.

Your HELIODENT^{PLUS} team

1.2 General information about this operating manual

Observe the Operating Instructions

Please familiarize yourself with the unit by reading through these Operating Instructions before putting it into operation. It is essential that you comply with the specified warning and safety information.

Keep documents safe

Always keep the Operating Instructions handy in case you or another user require(s) information at a later point in time. Save the Operating Instructions on the PC or print them out.

If you sell the unit, make sure that the Operating Instructions are included with it either as a hard copy or on an electronic storage device so that the new owner can familiarize himself with its functions and the specified warning and safety information.

Online portal for technical documents

We have set up an online portal for the Technical Documents at http://www.sirona.com/manuals. From here, you can download these Operating Instructions along with other documents. Please complete the online form if you would like a hard copy of a particular document. We will then be happy to send you a printed copy free of charge.

Help

If you reach an impasse despite having thoroughly studied the operating instructions, please contact your dental depot.

1.3 Contact information

Customer service center

In the event of technical queries, please use our online contact form at www.sirona.com. In the navigation bar, go to the menu commands *"CONTACT"* | *"Customer Service Center"* and then click the *"CONTACT FORM FOR TECHNICAL QUESTIONS"* button.

Manufacturer's address

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64625 Bensheim
Germany

Phone: +49 (0) 6251/16-0
Fax: +49 (0) 6251/16-2591
e-mail: contact@sirona.com
www.sirona.com

1.4 Warranty and liability

Maintenance

In the interest of the safety and health of patients, users and other persons, inspection and preventive maintenance must be performed at scheduled intervals to ensure the operational reliability and functional safety of your product (IEC 60601-1 / DIN EN 60601-1 etc.).

The system owner must ensure that all inspections and maintenance events take place.

As manufacturers of medical electrical equipment, we can assume responsibility for the safety properties of the system only if maintenance and repair work on the system is performed by ourselves or by agencies expressly authorized by us, and if components affecting safe operation of the system are replaced by original spare parts in case of failure.

Exclusion of liability

If the system owner fails to fulfill the obligation to have inspections and maintenance work performed or ignores error messages, Sirona Dental Systems GmbH and its authorized dealers cannot assume any liability for resulting damage.

Certificate of work

We suggest that you request a certificate, showing the nature and extent of the work performed, from those who carry out such work, and specify that the certificate show any changes in rated parameters or working ranges, as well as the date, the name of the firm and a signature.

1.5 Intended use

This system must not be used in areas subject to explosion hazards.

The HELIODENT^{PLUS} is an extraoral X-ray system. It is intended for use in dental radiographic examination and diagnosis of diseases and disorders of the teeth, the jaw and oral structures.

With room temperatures > 35°C (> 95°F) Sirona recommends the use of an air conditioning system.
Recommended operating temperature: 18 °C - 35 °C (64 °F - 95 °F)

United States only
CAUTION Federal law (USA) restricts sale of this device to or on the order of a physician, dentist, or licensed practitioner.

1.5.1 Indication and contraindication

Indications in the areas:

- Conservative dentistry
- Caries diagnosis, especially of proximal lesions
- Endodontics
- Periodontology
- Prosthodontics
- Functional diagnosis and therapy of craniomandibular dysfunctions
- Surgical dentistry
- Implantology
- Oral and maxillofacial surgery
- Orthodontics

Contraindications:

- Display of cartilage structures
- Display of soft tissue

1.6 Structure of the document

1.6.1 Identification of the danger levels

To prevent personal injury and material damage, please observe the warning and safety information provided in the present operating instructions. Such information is highlighted as follows:

⚠ DANGER

An imminent danger that could result in serious bodily injury or death.

⚠ WARNING

A possibly dangerous situation that could result in serious bodily injury or death.

⚠ CAUTION

A possibly dangerous situation that could result in slight bodily injury.

NOTICE

A possibly harmful situation which could lead to damage of the product or an object in its environment.

IMPORTANT

Application instructions and other important information.

Tip: Information on making work easier.

1.6.2 Formats and symbols used

The formats and symbols used in this document have the following meaning:

✓ Prerequisite **1.** First action step **2.** Second action step or ➢ Alternative action ↳ Result ➢ Individual action step	Requests you to do something.
See "Formats and symbols used [→ 8]"	Identifies a reference to another text passage and specifies its page number.
• List	Designates a list.
"Command / menu item"	Indicates commands, menu items or quotations.

2 Safety information

2.1 Information on the unit

Accompanying documents

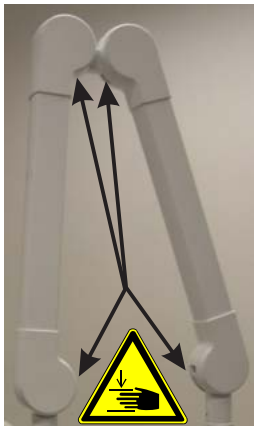
This symbol is affixed next to the unit rating plate.

Meaning: When operating the unit, observe the operating instructions.

This symbol is affixed on the unit rating plate.

Meaning: The accompanying documents are available on the homepage of Sirona.

2.2 Risk of crushing



⚠ CAUTION

Gaps appear between the internal hinges when moving the angular support arm.

Fingers may be crushed in these gaps.

➢ Ensure that you never place your fingers in the gaps between the hinges, neither during operation nor for cleaning purposes.

2.3 Maintenance

In the interest of the safety and health of patients, users and other persons, inspection and preventive maintenance must be performed at scheduled intervals to ensure the operational reliability and functional safety of your product (IEC 60601-1 / DIN EN 60601-1 etc.).

The system owner must ensure that all inspections and maintenance events take place.

If the system owner fails to fulfill the obligation to have inspections and maintenance work performed or ignores error messages, Sirona Dental Systems GmbH and its authorized dealers cannot assume any liability for resulting damage.

As manufacturers of medical electrical equipment we can assume responsibility for the safety-related features of the equipment only if **maintenance and repair** are carried out only by ourselves or agencies expressly authorized by us, and if components affecting safe operation of the system are replaced with **original spare parts** upon failure.

We suggest that you request a certificate showing the nature and extent of the work performed from those who carry out such work; it must contain any changes in rated parameters or working ranges (if applicable), as well as the date, the name of the company and a signature.

2.4 Modifications to the product

Modifications to this product which may affect the safety of the operator, patients or third parties are prohibited by law!

2.5 Condensation

Extreme fluctuations of temperature may cause condensation inside the unit. Do not switch the unit on before it has reached normal room temperature. See the chapter on “Technical data”.

2.6 Qualifications of operating personnel

The system may only be operated by skilled or properly trained personnel.

2.7 Radiation protection

The valid radiation protection regulations and measures must be observed. The statutory radiation protection equipment must be used. In order to reduce radiation exposure, Sirona recommends using bismuth or lead shields or aprons, especially for pediatric patients.

During an exposure, the operator should move as far away from the X-ray tube assembly as the coiled cable of the manual release permits.

With the exception of the patient, no other persons without radiation protection are allowed to stay in the room during an exposure. In exceptional cases, a third person may provide assistance, but not the practice staff.
If the patient is within reach of the unit including its operating elements, they must be supervised. Visual contact with the patient and the unit must be maintained throughout the entire exposure.

In case of malfunctions, cancel the exposure immediately by letting go of the exposure release button.

2.8 Hygiene

Suitable hygienic measures must be taken to prevent cross contamination among patients, operators and other persons.

Before positioning the patient in the unit, you must ensure that

- all auxiliary X-ray equipment is used and prepared (sterilized and/or disinfected) in accordance with manufacturer specifications (e.g. hygienic protective sleeves).

Compliance with the hygienic measures prevents the transmission of infections that can trigger severe illnesses.

2.9 Trouble-free operation

Use of this system is permissible only if it works properly without malfunctions. If trouble-free operation cannot be ensured, the unit must be taken out of service, checked by authorized technicians for malfunctions and, if necessary, repaired.

The device may only be operated with a complete cover and protective hood.

2.10 Interference with electronic devices

To prevent the malfunctioning of electronic devices and data storage devices, e.g. radio-controlled watches, telephone cards, etc., these objects must be removed prior to X-raying.

2.11 Risks of electromagnetic fields

The function of implanted systems (cardiac pacemakers or cochlear implants, for example) can be affected by electromagnetic fields. Before commencing treatment, ask if the patient has a cardiac pacemaker or any other implanted system.
Any prevailing risks are listed in the documentation provided by the equipment manufacturer.

2.12 Electromagnetic compatibility

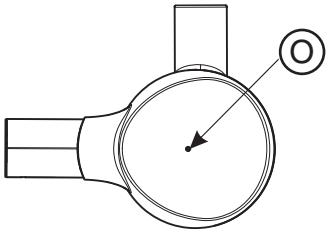
The acquisition unit complies with the requirements of the standard IEC 60601-1-2.

Medical electrical devices are subject to special precautionary measures with regard to EMC. It must be installed and operated as specified in the document “Installation Requirements”.

Portable and mobile RF communications equipment may interfere with medical electrical equipment.

3 Technical description

3.1 Technical data

Nominal voltage:	120V, 200V– 240V
Permissible fluctuation:	± 10%
Rated current:	At 120 V: 10A
	At 200 – 240 V: 6 – 5 A
Nominal frequency:	50 Hz / 60 Hz
Internal line impedance:	At 120 V 0.3 ohms
	At 200 – 240 V 0.8 Ohm
Main building fuse:	16 A slow blow
Power input during radiation:	1.2 kW
Power input in standby mode:	< 20 W
Tube voltage:	60 kV / 70 kV switchable (max. tolerance ± 5 kV)
Tube current:	7 mA (max. tolerance ± 1.4 mA)
High-voltage waveform:	DC high frequency residual ripple value ≤ 4 kV
High voltage generation frequency:	50 kHz - 70 kHz
Radiation time:	0.01 – 3.2 s (max. tolerance ± 10% +1 ms)
Pulse/pause ratio:	automatic monitoring from 1:1 to 1:60
Total filtration of X-ray tube assembly:	> 1.5 Al / 70 IEC 60522
Radiation field:	Ø < 60 mm
Dose rate:	8.5 mGy/s ±40% at 60 kV 11 mGy/s ±40% at 70 kV
Measuring instruments:	PTW Nomex with an ionization space of 1 cm^3 or Unfors mult-o-meter
Measuring conditions:	200 mm focus-meter space 230 V nominal voltage
Focal spot size as specified in IEC 60336:	0.4
Focal spot marking **O**:	

Source-skin distance:	FHA 200 mm (8") - standard or 300 mm (12")
Class I device Degree of protection against electric shock:	Type B device 
Degree of protection against ingress of water:	Ordinary equipment (without protection against ingress of water)
Year of manufacture:	 20XX (on the rating plate)
Operating mode:	Continuous operation

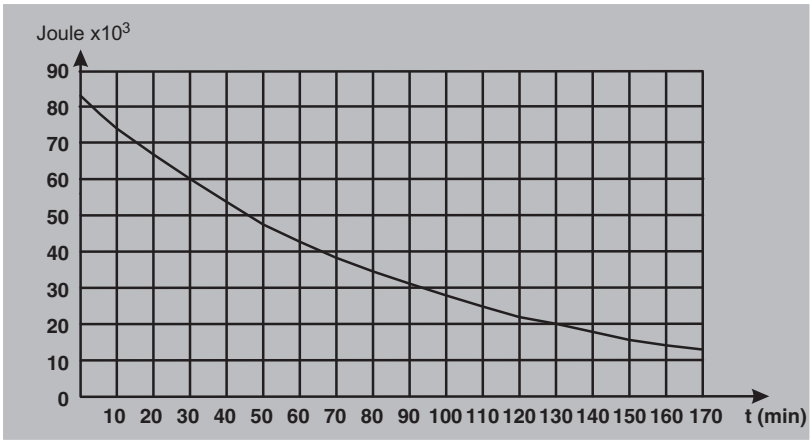
X-ray tubes:	Petrick P470/8.35/12G
Nominal continuous power rating of the X-ray tube:	26 W
Power rating of X-ray tube (70 kW/7 mA):	490 W
Anode material:	Tungsten
Anode angle:	12°
Exposure parameters for determining leakage radiation:	0.12 mA / 70 kV
Leakage radiation at 1 m distance:	< 0.25 mGy/h

Transport and operating conditions:

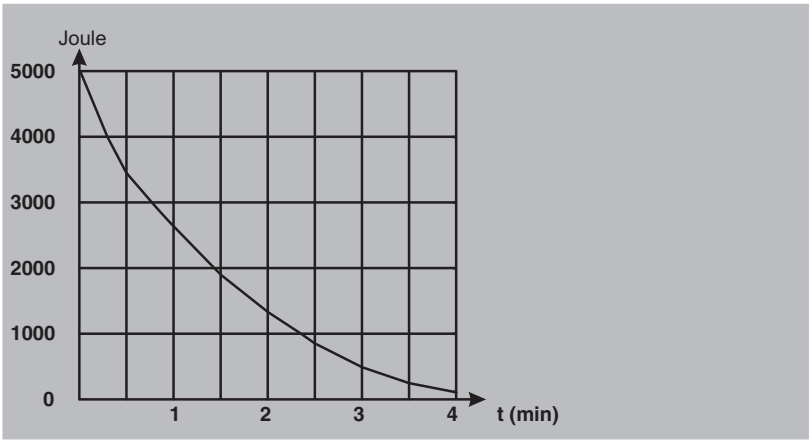
Transport and storage temperature:	-40°C – +70°C (-40°F – 158°F)
Air humidity:	10% – 95%
Operating conditions as specified in IEC 60601-1:	Ambient temperature +10 °C – +40 °C (50 °F – 104 °F)
	Relative humidity: 30% – 75%
Operating altitude:	≤ 3000 m

3.2 Diagrams

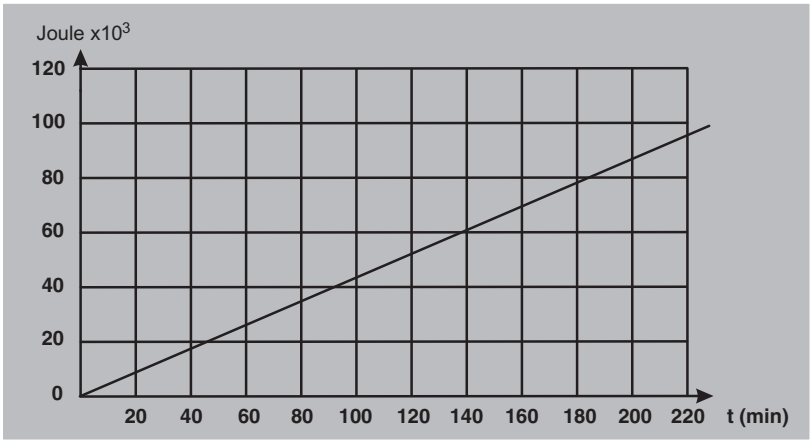
Cooling curve of tube housing



Cooling curve of X-ray tube



Heating curve of tube housing



3.3 Certification, registration and standards

The HELIODENT PLUS complies with the following standards, among others:

- IEC 60601-1
- IEC 60601-1-3
- IEC 60601-2-65

  The dental X-ray equipment for intraoral radiography HELIODENT PLUS D3507 complies with IEC 60601-2-65.

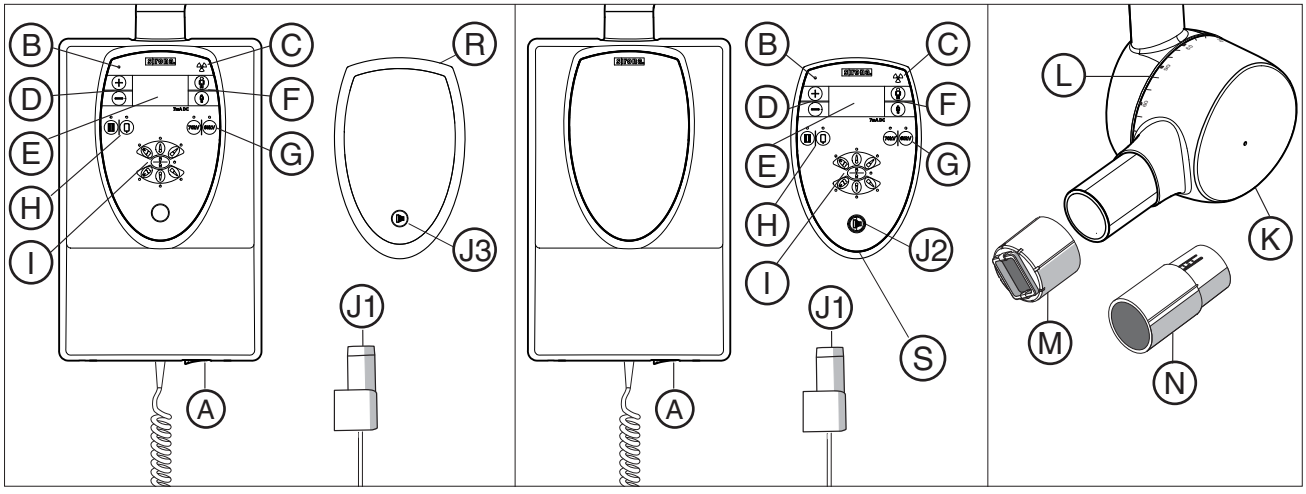
Original language: German

CE 0123

This product bears the CE mark in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices (MDD).

4 Controls and functional elements

4.1 Operating and Display Elements



A	Main ON/OFF switch	
B	Readiness for operation indicator (LED)	
C	Optical radiation indicator for X-ray	
D	Plus/minus keys for exposure time	
E	Digital display of exposure time	
F	Child/Adult pre-selection key	
G	Pre-selection keys and display of 60 kV/70 kV	
H	Pre-selection keys and display of digital mode and film mode	
I	Keys and display for tooth selection/image type	
J1	Manual release J1	Depending on the installed version
J2	Release button J2 on the Remote Timer	
J3	Release button J3 on the remote control	
K	X-ray tube unit	
L	Scale for adjusting the angle of inclination	
M	Radiation field limitation	
N	Cone extension	
R	Remote control	
S	Remote Timer	

4.2 Meaning of the icons

Patient symbol

Adult

Child

Plus key

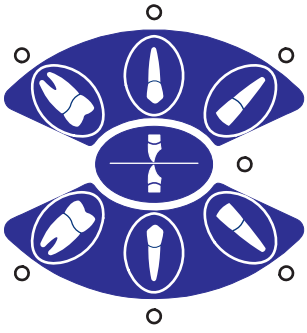
Minus key

Exposure release button

Maxillary front tooth

Maxillary canine/premolar

Maxillary molar



Bite-wing exposure

Mandibular front tooth

Mandibular canine/premolar

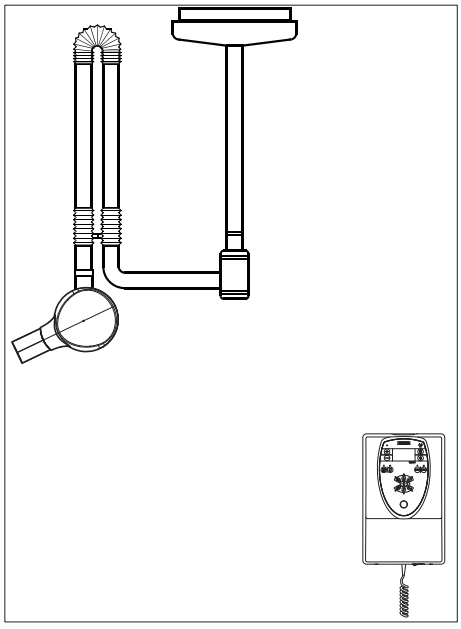
Mandibular molar

4.3 Display structure

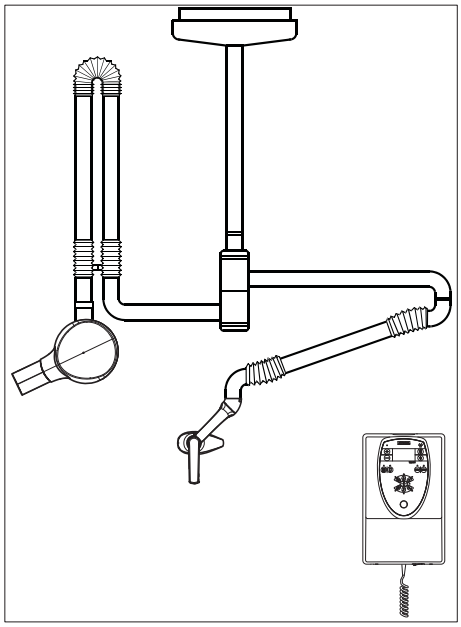
The background lighting of the display indicates the current status of the unit.

Background color	Meaning
Blue	Ready for radiation
Yellow	Radiation
White	Service
Red	Error

4.4 Version Ceiling model/Ceiling combination



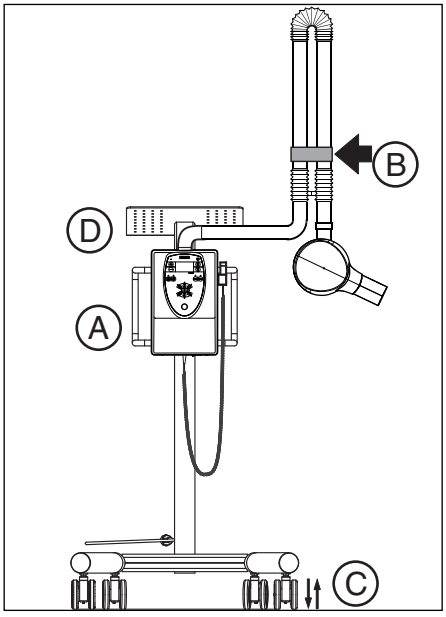
Ceiling model



Ceiling combination with LEDview

4.5 Mobile stand variant

Mounting of the wall model with round or angular support arm (only support arm length short possible) on a mobile stand for mobile use.



Secure the tube assembly with the fastening strap (B).

Use the two handles (A) on the side to move the mobile stand.

The mobile stand must be moved **slowly** on an **even** surface.

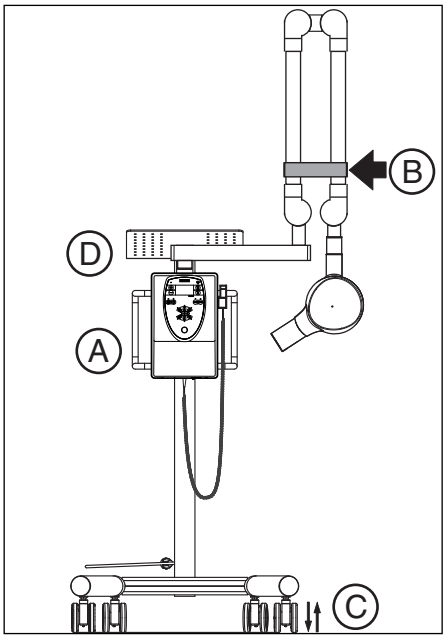
⚠ CAUTION

Risk of injury!

When changing the treatment station, the stay arm must be secured with the fastening strap provided (B).
The mobile stand must be moved extremely carefully using the handholds provided (A).
Particular care must be taken when crossing floor beams. The mobile stand may need to be lifted a little if necessary.

The mobile stand has 4 rollers with brakes.

To lock the rollers in place, press the locking lever (C) down ↓ , and to release lift it up ↑ .



⚠ CAUTION

Always apply the brakes (C) before setting up the X-ray tube assembly.

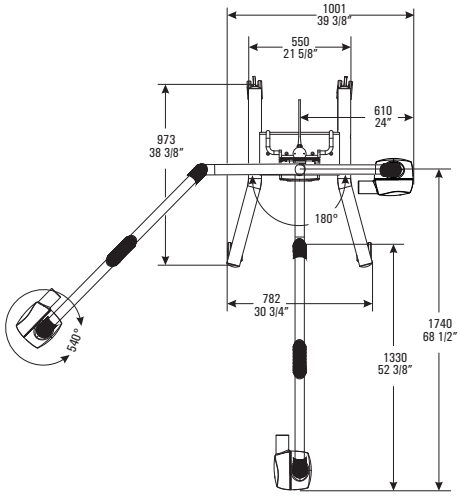
The mobile stand can be fitted with a tray (D).

⚠ CAUTION

This tray may hold a maximum of 5 kg.

End stop

Rotation option of the round/angular support arm is 180°.



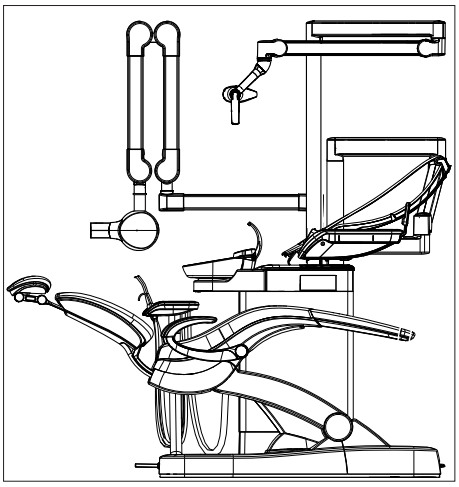
⚠ CAUTION

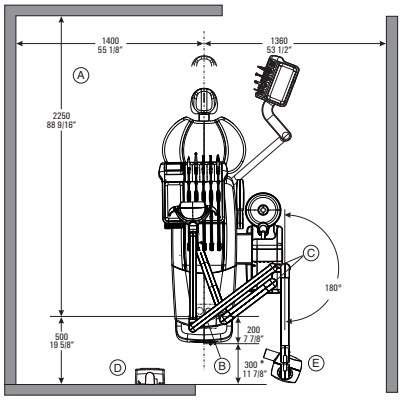
When the angular support arm moves, gaps are created between the support arm and the tray.

Fingers can be crushed in these gaps.

➢ Be careful not to put your fingers in the space between the moving arm and the tray, either during operation or when cleaning.

4.6 Version Unit model





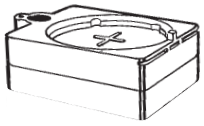
HELIODENT Plus at a treatment center, only possible with angular support arm system.

Rotation option of the angular support arm is 180°.

4.7 Accessories

IMPORTANT

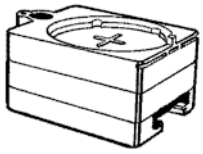
Not all of the accessories listed here are included in the scope of supply.



Only required in countries in which the constancy test is mandatory.

Phantoms for consistency checks on conventional imaging technology

Order No. 59 69 779

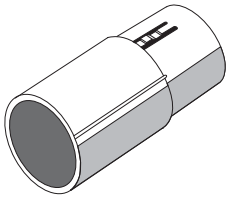


Only required in countries in which the constancy test is mandatory.

Phantoms for consistency checks on the Sirona XIOS XG sensor
Order no. 64 00 449

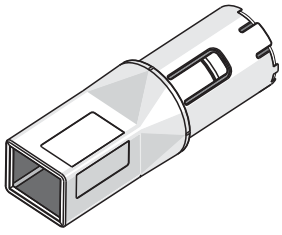
Phantoms for consistency checks on the Sirona XIOSPlus sensor
Order no. 62 09 634

Phantoms for consistency checks on the Sirona XIOS sensor
Order no. 61 37 447



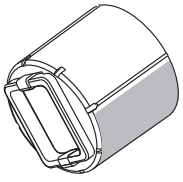
Cone extension to 300 mm FHA (12")

Order No. 62 41 983



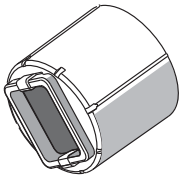
Square cone extension to 300 mm FHA (12")

Order No. 62 41 975



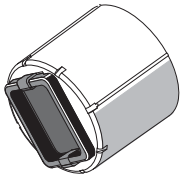
Radiation field limitation **white** size 0 with rotary handle for Sirona XIOS XG size 0 sensor and conventional imaging technology

Order No. 64 00 142



Radiation field limitation **blue** 3 x 4 cm with rotary handle for Sirona XIOS XG size 2 sensor, Sirona XIOS^{Plus}/XIOS size 2 sensor and conventional imaging technology

Order No. 62 41 991



Radiation field limitation **black** 2 x 3 cm with rotary handle for Sirona XIOS XG size 1 sensor, Sirona XIOS^{Plus}/XIOS size 1 sensor and conventional imaging technology

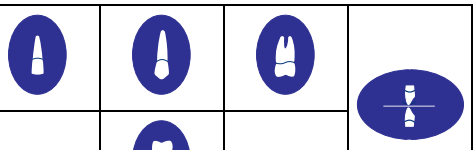
Order No. 62 42 007

4.8 Exposure times

4.8.1 Possible exposure times in seconds

0,01	0,02	0,03	0,04	0,05	0,06	0,08	0,10	0,12	0,16	0,20	0,25	0,32	0,40	0,50	0,64	0,80	1,00	1,25	1,60	2,00	2,50	3,20

4.8.2 Pre-programmed exposure times for films of sensitivity class E and with a 200 mm (8") FHA cone

	Upper jaw								
	Lower jaw								
	Upper jaw								
	Lower jaw								
Exposure time in seconds with:									
60 kV		0,06	0,08	0,10	0,12	0,16	0,20	0,25	0,32
70 kV		0,03	0,04	0,05	0,06	0,08	0,10	0,12	0,16
Freely programmed values									

NOTICE

For film of sensitivity class F: Set the exposure time one level lower with the minus button.
For films of sensitivity class D: Set the exposure time four levels higher with the plus button.
Using a film holder: Set the exposure time one or two levels higher with the plus button.

4.8.3 Pre-programmed exposure times for films of sensitivity class E and with a 300 mm (12") FHA cone

	Upper jaw								
	Lower jaw								
	Upper jaw								
	Lower jaw								
Exposure time in seconds with:									
60 kV		0,12	0,16	0,20	0,25	0,32	0,40	0,50	0,64
70 kV		0,06	0,08	0,10	0,12	0,16	0,20	0,25	0,32
Freely programmed values									

NOTICE

For film of sensitivity class F: Set the exposure time one level lower with the minus button.
For films of sensitivity class D: Set the exposure time four levels higher with the plus button.
Using a film holder: Set the exposure time one or two levels higher with the plus button.

4.8.4 Pre-programmed exposure times for XIOS XG sensors with 200 mm (8") FHA cone

Possible exposure times in seconds

The recommended exposure times are limited to the following values selected from the possible exposure times:

0.01	0.02	0.03	0.04	0.05	0.06	0.08	0.10	0.12	0.16	0.20	0.25	0.32	0.40

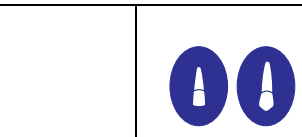
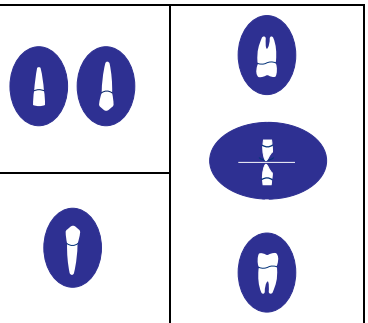
	Upper jaw					
	Lower jaw					
	Upper jaw			 		
	Lower jaw					
Exposure time in seconds with:						
60kV		0.06	0.08	0.10	0.12	0.16
70kV		0.03	0.04	0.05	0.06	0.08
Freely programmed values						

4.8.5 Pre-programmed exposure times for XIOS XG sensors with 300 mm (12") FHA cone (round or square cone)

Possible exposure times in seconds

The recommended exposure times are limited to the following values selected from the possible exposure times:

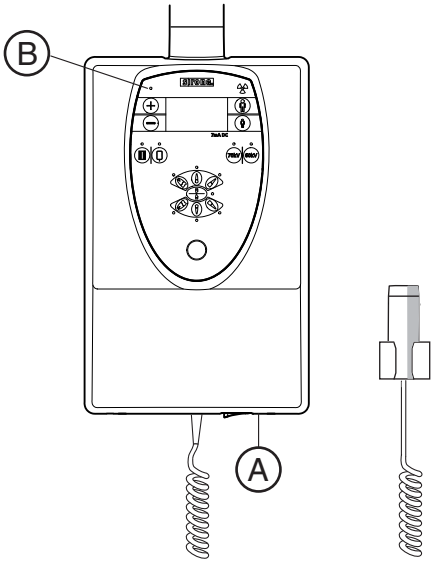
0.03	0.04	0.05	0.06	0.08	0.10	0.12	0.16	0.20	0.25	0.32	0.40	0.50	0.64	0.80

	Upper jaw					
	Lower jaw					
	Upper jaw					
	Lower jaw					
Exposure time in seconds with:						
60kV		0.12	0.16	0.20	0.25	0.32
70kV		0.06	0.08	0.10	0.12	0.16
Freely programmed values						

5 Operation

5.1 Preparing the exposure

5.1.1 Switch the unit on



Switch on the unit with the main switch (A) (Position I).

During this process none of the keys of the operating panel must be pressed.

After the unit is switched on, a self-test runs.
After approximately 20 seconds, the operational readiness LED (B) is continuously lit and the background lighting of the display changes to blue. The most recent exposure parameters set are displayed.

The unit is ready for radiation.

NOTICE

Error message after the self-test

If an error was detected during the self-test, a corresponding error code is shown on the display. (See chapter entitled "Error Messages"). The LED (B) flashes and the background lighting changes to red. The unit is not ready for operation.

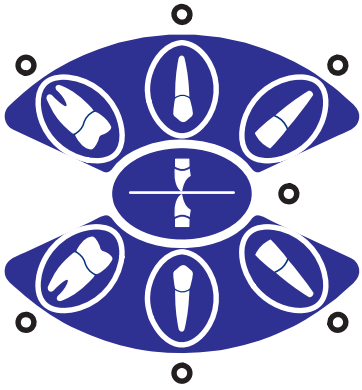
Switch unit OFF and ON again at the main switch (A).

⚠ CAUTION

Error message after a repeated self-test

If the error re-occurs, please call your service engineer.

5.1.2 Selecting the tooth icon



Press the key with the tooth icon to denote the region in which you want to take an X-ray.

The programmed exposure time is indicated.

The LED above/below the tooth icon lights up. During bite-wing exposures, the LED to the right of the icon lights up.

5.1.3 Selecting the patient symbol

Press the button with the adult patient icon if you wish to take an X-ray of an adult.

The programmed exposure time is indicated.

Press the button with the child patient icon if you wish to take an X-ray of a child.

The programmed exposure time is indicated.

5.1.4 Checking the kV value:

Check to see which kV value is set.

Press the 60 kV key to switch to 60 kV.

The exposure time for greater contrast is displayed.

Press the 70 kV button to switch to 70 kV.

The exposure time for enhanced detail recognition with a low level of exposure to radiation is displayed.

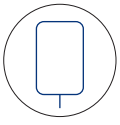
5.1.5 Plus/Minus keys

If you want to increase the exposure time, press the key with the plus symbol until the desired value is displayed.

If you want to decrease the exposure time, press the key with the minus symbol repeatedly until the desired value is displayed.

IMPORTANT
The LEDs above/below the tooth icon previously selected and the patient icon on the display go out.

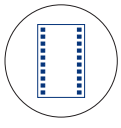
5.1.6 Checking the imaging technology



If you are working with a digital imaging system (e.g. XIOS XG), the sensor indicator should be lit on the unit. To switch, press the key with the sensor icon.

The exposure time for digital images is displayed.

Set the radiation field limitation for digital imaging technology.



If you wish to take conventional X-ray images (with film), the film indicator should light up on the unit. To switch, press the key with the film icon.

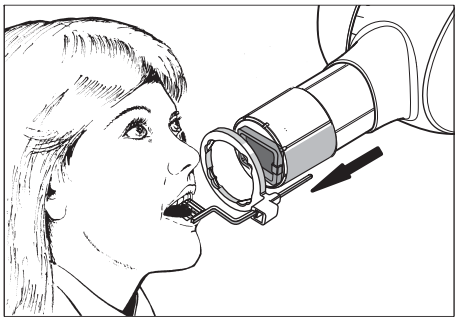
The exposure time for conventional exposures is displayed.

Set the radiation field limitation for conventional imaging technology.

5.2 Positioning the patient/X-ray tube assembly

Ask the patient to take a seat on the chair.
The operating elements of the unit should be out of reach of the patient.

Touch the tube assembly with both hands to position the tube.

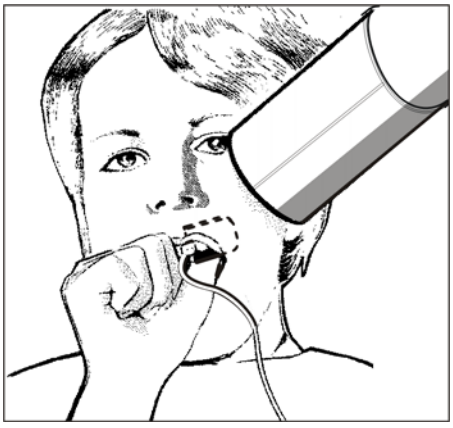


- **Parallel technique (with radiation field limitation)**

  Position the film or the X-ray sensor using a holding system for the parallel technique.

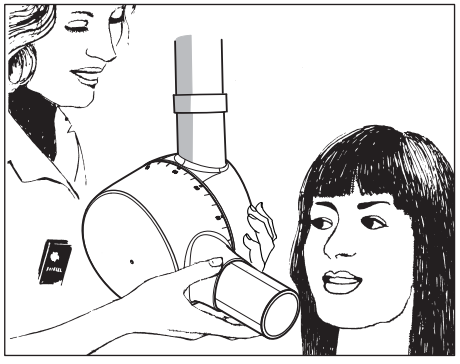
  For Sirona X-ray sensors, only the holding systems recommended by Sirona may be used.

  Please comply with the operating instructions for intraoral X-rays supplied with the sensors or films.



- **Half-angle technique (without radiation field limitation)**

  Position the film or the X-ray sensor.



- **Tilt angle**

  X-ray tube assembly at the occlusal plane

Upper jaw

Molars	35°
Premolars and canines	45°
Anterior teeth	55°
Bite-wing exposure	10°
---	---
Bite-wing exposure	-0°
Anterior teeth	-20°
Premolars and canines	-10°
Molars	-5°

Lower jaw

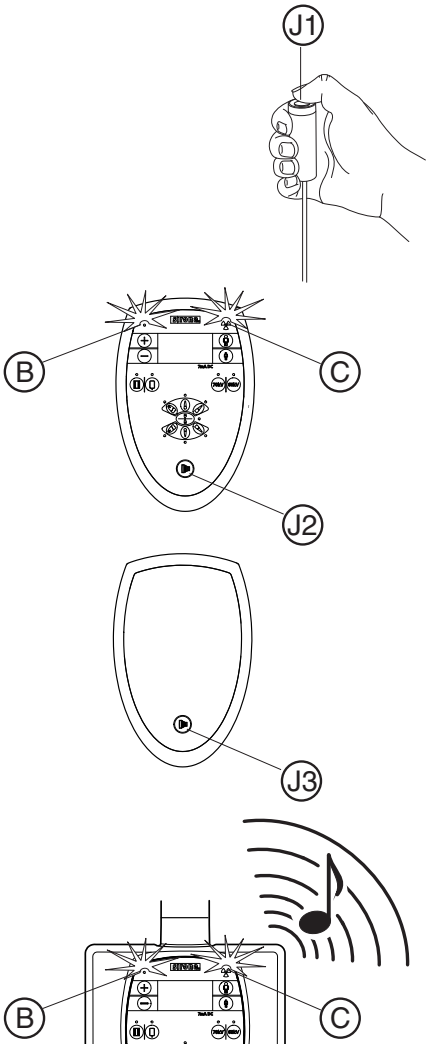
5.3 Releasing the exposure

⚠ CAUTION

Comply with the radiation protection provisions.

NOTICE

When using a digital sensor system, establish exposure readiness in SIDEXIS before you release the exposure, see SIDEXIS User Manual.



- Check the exposure data.
- Keep the patient and unit in sight.
- Press and hold down the release key **J1, J2 or J3**. The exposure is taken.

The (**X-RAY**) indicator **C** remains lit for the duration of the exposure. In addition, an acoustic signal sounds throughout the entire radiation time.

- The exposure has been completed when the radiation indicator goes out automatically and the acoustic signal stops.
- If the dose area product display is activated, the dose area product appears on the display.

If the release key is pressed again, the cooling-off period appears on the display The screen is then white.

The operational readiness LED **B** flashes until the automatic cooling-off period of the X-ray tube assembly has expired (automatic exposure block).

Canceling an exposure

If you let go of the exposure release button prematurely, the exposure is canceled. The elapsed exposure time flashes.
If the device is switched off at the main switch, the exposure is also canceled.

After any key (except for the release button) is pressed, the cooling time starts and the unit is once again ready for operation.

Repeat the X-ray if necessary.

If you are taking an X-ray with film, use a new film.

If you are taking a digital X-ray, ensure that the unit is ready to perform exposures.

NOTICE

Error message

If an error is detected during the exposure, the exposure is automatically canceled. The error code lights up on the digital display. At the same time, the operational readiness LED **(B)** flashes.
In the case of an error code, please call your service engineer.

IMPORTANT

Switch off

If the device is out of use for a lengthy period of time, it can be switched off at the main switch.

5.4 Adapting basic settings

Exposure times for the use of films with the sensitivity class E are factory pre-set, as well as the XIOS XG sensors.

IMPORTANT

The exposure times for sensor and film images are programmed separately. The factory pre-set sensor programming is configured for XIOS XG sensors.

The basic setting must be adjusted for other exposure conditions.

Deviating exposure conditions:

E for films of sensitivity class **E** such as Kodak Ekta Speed, Agfa-Dentus M2

D for films of sensitivity class **D** such as Kodak Ultra Speed

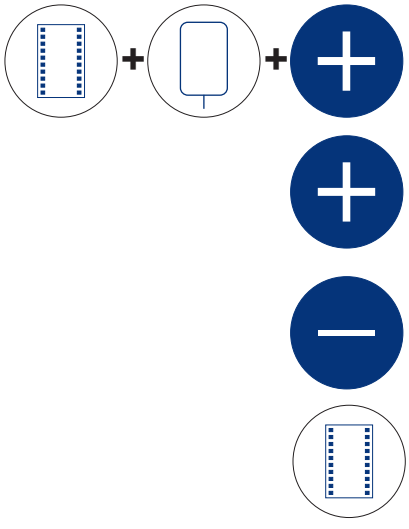
Set the exposure time for films of sensitivity class **D** three levels higher with the plus button.

Film and development conditions

Varying film and development conditions can result in additional deviations of one time level up or down.

IMPORTANT

The configuration of the film and sensor keys permits flexible adjustment to various film sensitivity classes and sensors. It is also possible to set up the exposure adjustment for another film sensitivity class via the sensor key, if no sensor is being used.



✓ Reprogramming the base values

1. Press the **film**, **sensor** and **plus buttons at the same time**.
   Service S01 appears in the display.

2. Use the plus **or** minus key to select the base value that is to be changed:
   S01 corresponds to the base value for film
   S02 corresponds to the base value for sensor
   S03 corresponds to the software version

3. Confirm the entry with the Film key.
   The current base value for film or sensor is now displayed:

4. The base value can now be adjusted by pressing the plus or minus buttons.
   Each level corresponds to about a 25% extension or reduction in exposure time.
5. The entry can be confirmed by pressing the button with the adult patient icon. The new base value is now saved in the unit.
   To cancel this without changing, press the button with the child patient icon.
   In either case you will return to point 2 and can select the required base value again
   or
   conclude the process by switching the device off.

6 Maintenance

6.1 Cleaning and care

6.1.1 Cleaning

Remove dirt, grime and disinfectant residue regularly using mild, commercially available cleaning agents.

NOTICE

During cleaning or disinfection, liquids may enter the manual release button or unit via ventilation slots.

Electrical components of the system can be destroyed by liquids.

- ➢ Do not spray any liquids into the ventilation slots or manual release button.
- ➢ First spray the liquid onto a cleaning cloth. Then wipe the ventilation slots or manual release button with the cleaning cloth.
- ➢ Make sure that no liquids run along the surface and into the ventilation slots or the manual release button.

6.1.2 Disinfecting

Only the external surfaces may be disinfected with approved chemical disinfectants. Use only disinfectants that comply with the valid requirements of the respective national regulatory body or whose bactericidal, fungicidal and virucidal properties have been verifiably tested and approved accordingly.

⚠ CAUTION

Cleaning and care agents may contain aggressive ingredients.

Unsuitable cleaning and care agents are detrimental to health and attack the surface of the unit.

- ➢ Do NOT use: Substances containing phenol, peracetic acid, peroxide or any other oxygen-splitting agents, sodium hypochlorite or iodine-splitting agents.
- ➢ Use only cleaning and disinfecting agents approved by Sirona!

A continuously updated list of approved agents can be downloaded from the Internet at:
"www.sirona.com" | "SERVICE" | "Care and cleaning" | "Care and cleaning agents"

If you do not have any access to the Internet, you can order the list in one of the following two ways:

- Order from your local dental depot
- Order from Sirona:
  Tel: ++49 (0) 62 51 / 16-16 70
  Fax: ++49 (0) 62 51 / 16-18 18

REF **59 70 905**

Sirona recommends the following disinfectants:

- MinutenSpray classic, by ALPRO®
- MinutenWipes, by ALPRO®

In the USA and Canada:

- CaviCide® or
- CaviWipes ™ .

6.1.3 Maintenance of accessories

IMPORTANT
With regard to accessories, particularly those of sensor and film holder systems, please comply with the cleaning and care instructions in the relevant operating instructions.

6.2 Inspection and maintenance

Inspection and preventive maintenance must be performed at scheduled intervals to protect the health and safety of patients, users and other persons.

The information provided in the document *"Inspection and maintenance and safety-related checks"* REF 62 14 923 should be helpful here. The document can be downloaded at http://www.sirona.com/manuals.

Annual inspection

In order to ensure the operational safety and functional reliability of your product, you as the system owner should check the equipment at regular intervals (at least once a year) or commission your dental depot to do so.

Maintenance by the service engineer

In addition to the annual check to be carried out by the system owner or authorized persons, preventive maintenance must be performed after 4, 7 and 10 years, and then at two-year intervals.

Image quality check

The image quality should be assessed by the system owner at regular intervals, at least once a year.

On digital image receptor systems, the degree of postprocessing (brightness or contrast adjustment) that is required in the image processing software (e.g. SIDEXIS) to produce satisfactory results is used as an assessment criterion.

For conventional X-rays with film processing, the increase of the exposure time is used as an assessment criterion.

If, after taking into account the patient's anatomy and excluding possible sources of error such as incorrect patient positioning, this criterion seems to apply, immediately contact a service engineer to have potential system faults repaired.

Country-specific requirements

Observe any possible additional country-specific requirements.

7 Error messages

Errors during the self-test are indicated by a five-digit number lighting up. The background color of the display is red.

⚠ CAUTION

If an error re-occurs after the unit has been switched off and switched on again, please call your service engineer.

Tell the service engineer which error message was displayed.

7.1 List of error messages

Error code	Reason and measures
E3 04 30	Release error - the release button may have been pressed during switch on Switch the device OFF and then ON again If the error persists, call a service engineer and report the error code
E1 11 88	Display mode ACTIVE - X-ray cannot be release Call a service engineer and report the error code
E1 04 03 E1 04 04 E1 04 06 E6 04 02	Internal error Press any button to acknowledge the error If the error persists, call a service engineer and report the error code
E5 04 50 E6 01 41 E6 01 61 E6 01 62 E6 04 01 E6 04 10 E6 04 11 E6 04 12 E6 04 20 E6 04 21 E6 04 40 E6 04 41 E6 04 42 E7 01 01 E7 01 21 E7 01 51	Internal error Switch the device OFF and then ON again and repeat the exposure If the error persists, call a service engineer and report the error code
E5 01 02 E5 01 12 E5 01 14 E5 01 22 E5 01 32 E5 01 42 E6 01 11 E6 01 13 E6 01 23 E6 01 31	Internal error Call a service engineer and report the error code

Error code	Reason and measures
E1 04 51	Safety circuit - the door switch may not be closed properly Switch the device OFF and then ON again, check the door switch If the error persists, call a service engineer and report the error code
E3 04 31	Button error - a button may have been pressed during switch on Switch the device OFF and then ON again If the error persists, call a service engineer and report the error code

8 Dismantling and disposal

8.1 Dismantling and reinstallation

When dismantling and reassembling the unit, proceed according to the installation instructions for new installation in order to guarantee its functioning and stability.

8.2 Disposal

Based on Directive 2012/19/EU and country-specific disposal directives for waste electrical and electronic equipment, we would like to point out that these must be disposed of in a special way within the European Union (EU). These regulations require environmentally compliant recycling/disposal of waste electrical and electronic equipment. They must not be disposed of as domestic waste. This is shown with the symbol of the crossed out dust bin, which has been in use since March 24, 2006.

Disposal procedure

We feel responsible for our products from the initial idea to their disposal. That is why we give you the option of taking back our waste electrical and electronic equipment.

If disposal is required, please proceed as follows:

In Germany

In order to arrange return of the electrical equipment, please send a disposal request to "enretec GmbH." The following options are available for this purpose:

- On the homepage of enretec GmbH, click on the "Return of electronic equipment" button under the "eom" menu item.
- Alternatively, you may also contact the company directly.

  enretec GmbH
  Kanalstraße 17
  16727 Velten

  Tel: +49 3304 3919-500
  Email: eom@enretec.de

As manufacturers, we assume the costs for disposal of waste from electrical and electronic equipment in accordance with the country-specific disposal regulations (ElektroG). All disassembly, transport and packaging costs are to be borne by the owner/operator.

Proper preparation (cleaning/disinfection/sterilization) of the equipment must be carried out prior to disassembly/disposal.

Any nonpermanently installed equipment will be picked up at its installation site in the practice. Permanently installed equipment will be picked up curbside at your address by appointment.

Other countries

The dental dealers would be glad to provide you with country-specific information.

8.2.1 Disposal of the X-ray tube assembly

The X-ray tube assembly in this device contains a tube which can implode, a lead lining and mineral oil.

9 Dose area product (DFP)

Information on patient exposure

Explanation

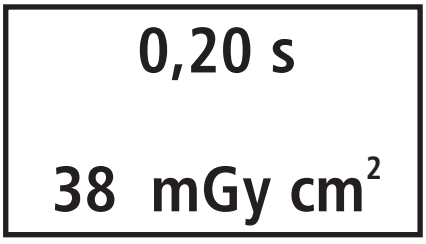
The patient's exposure to radiation can be determined in the tables below.

To compensate for measuring errors as well as for system and instrument variations, a tolerance of 20% must be taken into account.

The radiation exposure is indicated as a dose area product (DFP) of the energy dose (mGy x cm^2) for every available kV level, cone length and aperture in the tables below.

Furthermore, the HELIODENT^{PLUS} also permits the dose area product to be displayed immediately after exposure. The DFP appears on the display together with the exposure time used.
Ask your service engineer about any individual setting requests you may have.

Display (sample):



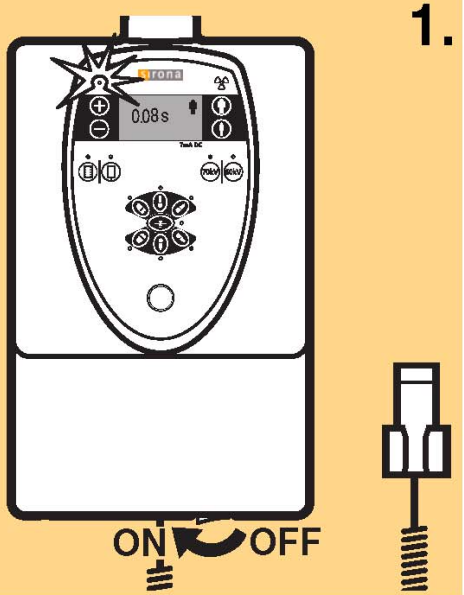
Calculation and definition of the dose area product for the HELIODENT^{PLUS}

Tables with typical values for the dose area product (DFP)

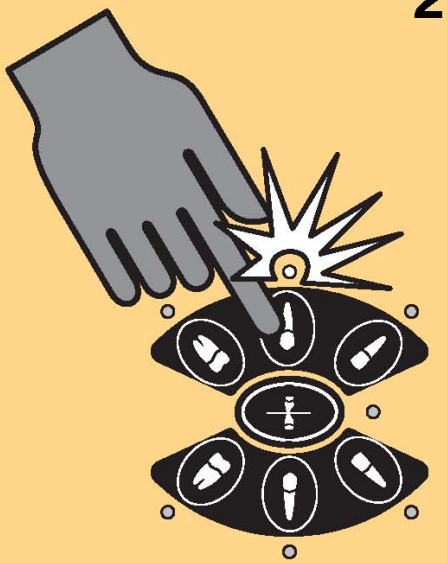
	Round cone:		with radiation field limitation			
	200 mm (8")		3x4		2x3	
	60 kV	70 kV	60 kV	70 kV	60 kV	70 kV
Time	mGy cm^2	mGy cm^2	mGy cm^2	mGy cm^2	mGy cm^2	mGy cm^2
0,01	3	3	1	1	1	1
0,02	5	7	2	3	1	1
0,03	8	10	3	4	2	2
0,04	11	14	5	6	2	3
0,05	13	17	6	7	3	4
0,06	16	21	7	9	3	4
0,08	22	28	9	12	5	6
0,10	27	34	12	15	6	7
0,12	32	41	14	18	7	9
0,16	43	55	18	24	9	12
0,20	54	69	23	30	12	15
0,25	67	86	29	37	14	18
0,32	86	110	37	47	18	24
0,40	108	138	46	59	23	30
0,50	134	172	58	74	29	37
0,64	172	220	74	94	37	47
0,80	215	276	92	118	46	59
1,00	269	344	115	148	58	74
1,25	336	431	144	185	72	92
1,60	430	551	184	236	92	118
2,00	538	689	230	295	115	148
2,50	672	861	288	369	144	185
3,20	860	1102	369	472	184	236

	Round cone:		with radiation field limitation			
	300 mm (12")		3x4		2x3	
	60 kV	70 kV	60 kV	70 kV	60 kV	70 kV
Time	mGy cm^2	mGy cm^2	mGy cm^2	mGy cm^2	mGy cm^2	mGy cm^2
0,01	1	2	1	1	0	0
0,02	3	3	1	1	1	1
0,03	4	5	2	2	1	1
0,04	5	7	2	3	1	1
0,05	7	9	3	4	1	2
0,06	8	10	3	4	2	2
0,08	11	14	5	6	2	3
0,10	13	17	6	7	3	4
0,12	16	21	7	9	3	4
0,16	22	28	9	12	5	6
0,20	27	34	12	15	6	7
0,25	34	43	14	18	7	9
0,32	43	55	18	24	9	12
0,40	54	69	23	30	12	15
0,50	67	86	29	37	14	18
0,64	86	110	37	47	18	24
0,80	108	138	46	59	23	30
1,00	134	172	58	74	29	37
1,25	168	215	72	92	36	46
1,60	215	276	92	118	46	59
2,00	269	344	115	148	58	74
2,50	336	431	144	185	72	92
3,20	430	551	184	236	92	118

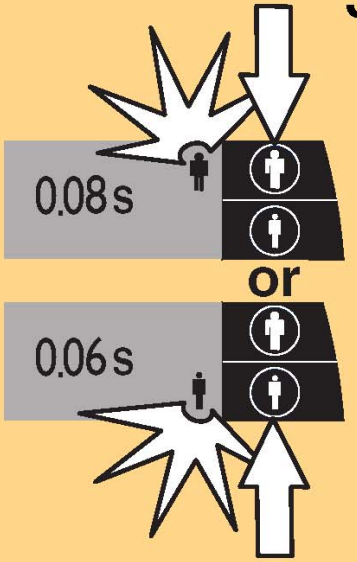
1.


0.08 s
ON
OFF

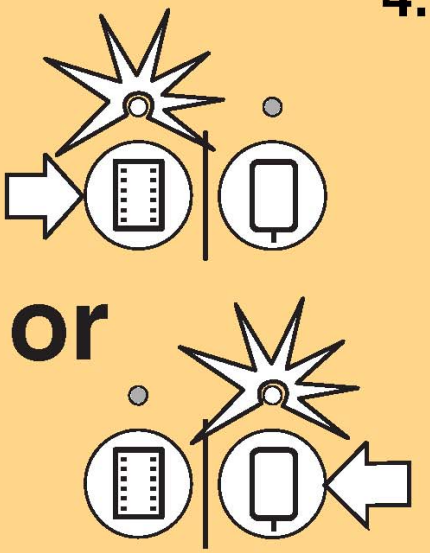
2.



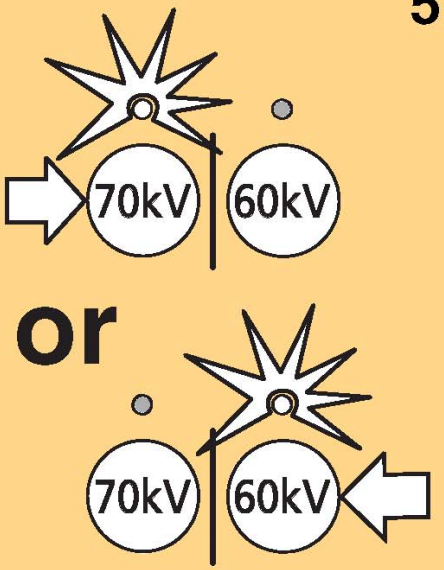
3.


0.08 s
or
0.06 s

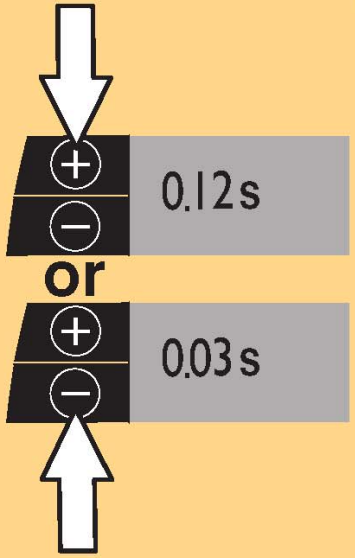
4.


or

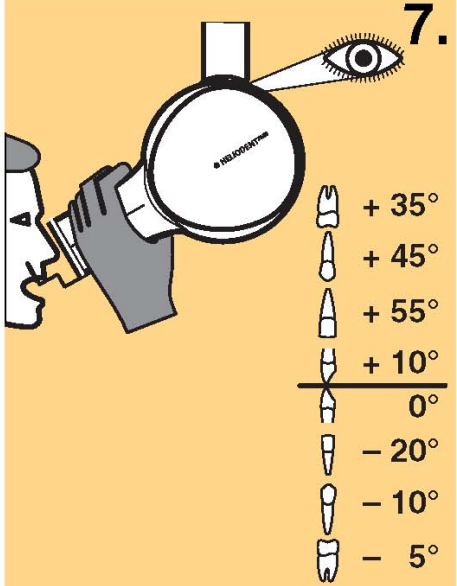
5.


70kV
60kV
or
70kV
60kV

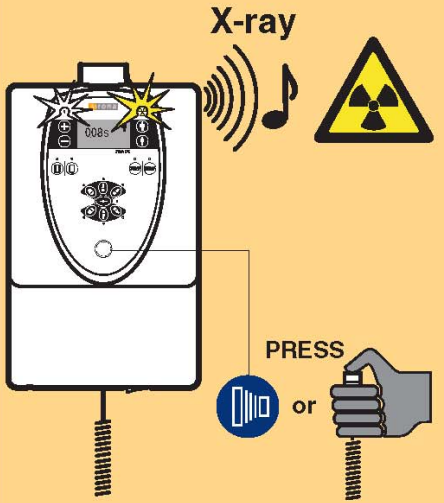
6.


0.12 s
or
0.03 s

7.


+ 35°
+ 45°
+ 55°
+ 10°
0°
– 20°
– 10°
– 5°

8.


X-ray
PRESS
or

We reserve the right to make any alterations which may be required due to technical improvements.

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